

Applicant: Yu, et al.	Examiner: Betty J. Forman	Office Action Mailed: 8/30/2006
Application S/N: 10/666,788	Group Art: 1634	Resp/Amend Date: 1/3/2007
Application Filed: 09/17/2003	Docket No: LSI0046/US/2	Page 4 of 7
Title: ELECTROCHEMICAL TEST STRIP FOR USE IN ANALYTE DETERMINATION		

### **Remarks**

Claims 21-26 are pending in the application. Reconsideration of the application in view of the remarks presented below is respectfully requested.

### **35 U.S.C. 103(a) Rejections**

*Claims 21-23 and 25-26 stand rejected under 35 U.S.C 103(a) as being unpatentable over Bamdad (US 6,306,584) and Ruger et al (US 5,834,224).*

The rejection under 35 USC 103(a) is based on the position of the Examiner that Bamdad teaches a homogeneous surface modification layer. As is demonstrated below, Bamdad fails to teach or suggest a homogeneous surface modification layer, and in fact teaches away from a homogeneous surface modification layer.

The modification layer disclosed in Bamdad is not homogeneous. More specifically, the modification layer is not homogeneous because it is made up of two different self-assembling molecules or SAMS. Specifically, Bamdad teaches a layer made up of first and second self assembling molecules that are mixed together and form a monolayer. For example, at col.3, lines 46-67 Bamdad states that:

According to a preferred aspect, the article is suitable for capturing a biological molecule. According to this aspect a self-assembled mixed monolayer, formed of a first species and a second species, is adhered to the surface. The first species has a formula X--R--Ch--M--BP, where X, R, Ch, M, and BP are each selected such that X represents a functional group that adheres to the surface, R represents a spacer moiety that promotes self-assembly of the mixed monolayer, Ch represents a chelating agent that coordinates a metal ion, M represents a metal ion, and BP represents a binding partner of the biological molecule. The binding partner is coordinated to the metal ion. The second species is selected to form a mixed, self-assembled monolayer with the first species, and according to a preferred aspect the second species has a formula, X--R--O--(CH<sub>2</sub>CH<sub>2</sub>--O)<sub>n</sub>--H, in which X represents a functional group that adheres to the surface, R represents a spacer moiety that promotes formation of a self-assembled monolayer of a plurality of the molecules, and n is from one to ten. The article can be constructed and arranged to facilitate instrumental determination of an analyte, and according to a preferred aspect is a biosensor element such as an SPR chip.

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Application S/N: 10/666,788	Group Art: 1634	Resp/Amend Date: 1/3/2007
Application Filed: 09/17/2003	Docket No: LSI0046/US/2	Page 5 of 7
Title: ELECTROCHEMICAL TEST STRIP FOR USE IN ANALYTE DETERMINATION		

Also, FIG. 18 provides a representation of Bamdad's surface modification layers which are shown as mixed SAM layers.

Because Bamdad teaches SAM layers that are mixtures of first and second SAMs, Bamdad fails to teach or suggest a homogeneous surface modification layer as claimed by applicant. That is, Bamdad's mixed SAM layer is not homogeneous because it is not made up of a single type of SAM.

The Office Action relies on the text at col. 5, lines 12-20 in support of the position that the kit comprises a single type of SAM. This text states:

The present invention also provides a kit including an article having a surface and a molecule X-R-CH, both as described above. The kit can include M and BP, either separately or combined as species X-R-Ch-M or X-R-Ch-M-BP, where X, R, Ch, M, and BP are as described herein. The kit also can include X-R-NA, optionally with NAB, or X-R-NA-NAB as described herein.

This first sentence of the referenced text simply states that the kit includes an article having a surface and a molecule X-R-CH, both as described above. The description above includes, for example, the text at col. 3, lines 46-67, which describes the self-assembled mixed monolayer as including both a first species and a second species (i.e., a mixed SAM layer). The second sentence of the referenced text states that M and BP can be separate (e.g., species X-R-Ch-M) or they may be combined (e.g., species X-R-Ch-M-BP). The phrase "either separately or combined" refers to the arrangement of M and BP groups on the molecule. The third sentence provides for the addition of certain other molecules to the surface layer. The referenced text does not teach or suggest a homogeneous made up of a single type of SAM.

The Office Action states that it would have obvious to one of ordinary skill in the art at the time the invention was made to apply the second end group of Ruger et al. to the test strip of Bamdad because sulfonate is the preferred end group for enzyme coupling. Applicant does not agree. Ruger et al. reports an electrochemical sensor containing a supporting material having a surface of a noble metal such as gold or palladium to which is bound an enzyme such as glucose oxidase via binding molecules. The binding molecules are in the form of a monolayer and are bound to the metal by anchor groups such as thiol, disulphide, or phosphine groups. Ruger et al. does not teach or suggest a homogenous surface modification layer made up of self assembling

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Application S/N: 10/666,788	Group Art: 1634	Resp/Amend Date: 1/3/2007
Application Filed: 09/17/2003	Docket No: LSI0046/US/2	Page 6 of 7
Title: ELECTROCHEMICAL TEST STRIP FOR USE IN ANALYTE DETERMINATION		

molecules. Specifically, Ruger et al. does not teach or suggest the use of self assembling molecules to form its surface layer. Rather, the binding molecules of Ruger et al. provide coverage on the surface that is less than the maximum coverage. This can be obtained by coating a solution having a low concentration of a single molecule or by using diluent molecule to provide coverage that is less than the maximum coverage. Since Ruger et al. is not concerned with the formation of a homogeneous surface modification layer comprising self assembling molecules, there would be no motivation to combine the teachings of Ruger et al. with Bamdad. In addition, even if combined, the suggested combination does not result in applicant's claimed invention since neither reference teaches or suggests a homogeneous surface modification layer comprising self assembling molecules.

In view of the foregoing, the rejection of claims 21-23 and 25-26 under 35 U.S.C. 103(a) as being unpatentable over Bamdad (US 6,306,584) in view of Ruger et al. (US 5,834,224) has been overcome and should be withdrawn.

*Claim 24 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Bamdad (US 6,306,584) and Ruger (US 5,834,224) as applied to Claim 21 and further in view of Blackman (US 4,813,538).*

Claim 24 depends from independent claim 21, and therefore includes all of the features of claim 21. Claim 21 is patentable for the reasons discussed hereinabove. Therefore, claim 24 is patentable for at least the same reasons. Accordingly, withdrawal of the rejection of claim 24 under 35 USC 103(a) as being unpatentable over Bamdad and Ruger et al. in view of Blackman should be withdrawn.

### **Double Patenting Rejection**

*Claim 26 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,716,577 in view of Bamdad (US 6,306,584) or Backhaus et al (US 5,869,001).*

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Application S/N: 10/666,788	Group Art: 1634	Resp/Amend Date: 1/3/2007
Application Filed: 09/17/2003	Docket No: LSI0046/US/2	Page 7 of 7
Title: ELECTROCHEMICAL TEST STRIP FOR USE IN ANALYTE DETERMINATION		

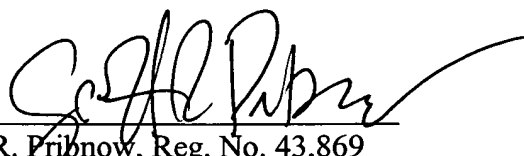
Upon notice that claim 26 is allowable over the art, applicant will timely file a terminal disclaimer over U.S. Patent No. 6,716,577 in order to overcome the nonstatutory obviousness-type double patenting rejection.

### **Conclusion**

In view of the foregoing, applicant submits that pending claims 21-26 are in condition for allowance. Allowance of claims 21-16 at an early date is respectfully requested.

Respectfully submitted,

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